EXPERT REPORT OF ROBERT L. HILL

In re National Prescription Opiate Litigation MDL No. 2804
Track One

May 31, 2019

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I. QUALIFICATIONS

1. My name is Robert L. Hill, and I am a retired government and pharmaceutical industry executive with over 25 years of experience as a Special Agent/Criminal Investigator with the United States Drug Enforcement Administration ("DEA"), which included over 14 years of management/executive positions. For the last six years of my career at DEA, I was assigned to the Office of Diversion Control at DEA Headquarters. From July 2012 to December 2014, when I retired, I served as the Executive Assistant to the Deputy Assistant Administrator, Office of Diversion Control. I am currently an independent consultant.

2. I earned a Bachelor of Science in Criminal Justice from Wayne State University in 1988.

3. I began my law enforcement career in August 1988 as a police officer in the City of Dearborn, Michigan. In September 1989, I became a DEA Special Agent in Detroit, Michigan. I conducted criminal and financial investigations against individuals and organizations that were suspected of violating the Controlled Substances Act ("CSA") and/or state narcotics statutes. From July 1996 to November 1998, I served as the Divisional Training Coordinator for DEA's Detroit Field Division, which covered Michigan, Ohio, and Kentucky.

4. In November 1998, I was reassigned to the Belize Country Office in Central America. I advised the U.S. Ambassador to Belize and the Belizean Government on counter-narcotics missions of the United States and Belize.

5. In April 2000, I returned to DEA's Detroit Field Division as a Group Supervisor for Enforcement Group III. I managed the day-to-day activities of twelve Special Agent/Criminal Investigators and two local police officers who were conducting criminal and financial investigations against individuals and organizations that were suspected of violating the CSA and/or state narcotics statutes. In addition, I assisted the Diversion Group in the Detroit Field Office, which is tasked with investigating registrants to ensure compliance with the CSA and its implementing regulations (Diversion Response Group).

6. In October 2005, I was reassigned to DEA Headquarters as a Staff Coordinator for the Latin America and Caribbean Section. There, I provided operational support and coordination to

assist foreign offices located in Latin America and the Caribbean in the development and furtherance of major drug and financial investigations.

7. In January 2009, I was promoted to Section Chief of the Pharmaceuticals Investigation Section. This section included the Targeting and Analysis Unit and the Pharmaceutical Investigations Unit. The Targeting and Analysis Unit reviewed Automation of Reports and Consolidated Orders System ("ARCOS") information and if it was deemed necessary leads would be sent out to the field for further investigation. The Pharmaceutical Investigations Unit would handle and/or assist investigations dealing with pharmaceutical controlled substances done in association with the field throughout the country.

8. In this role, I served as DEA's technical expert and provided programmatic oversight of enforcement strategies and operations aimed at stopping the diversion of pharmaceutical controlled substances. I also oversaw DEA's Tactical Diversion Squads Program, ARCOS, Drug Theft and Loss Database and Suspicious Orders Monitoring Program ("SOMP").

9. In July 2012, I was reassigned to be the Executive Assistant to the Deputy Assistant Administrator for the Office of Diversion Control. I assisted the Deputy Assistant Administrator with managing the day-to-day operations of the Office of Diversion Control. This included, but was not limited to: overseeing, coordinating and providing strategic direction to a DEA headquarters team of 300 personnel and 1,000 field personnel on all major regulatory, pharmaceutical, precursor chemical, clandestine laboratory and synthetic drug investigations; the issuance of administrative actions; the drafting and promulgating of regulations; establishing drug production quotas; preparing congressional testimony and briefing; conducting speaking engagements and media interviews; and serving as liaison to the pharmaceutical industry, international governments, state governments, federal agencies and law enforcement agencies. In December 2014, I retired from DEA.

10. From January 2015 until July 2018, I worked as the Director of DEA Compliance and Corporate Security for Amneal Pharmaceuticals. In this role, I ensured that all Amneal locations in Kentucky, New Jersey and New York that were authorized to handle controlled substances were in compliance with the Controlled Substances Act and its implementing regulations, as well as ensuring that appropriate security measures were in place to protect employees, facilities and

proprietary information. In my role, I also managed Amneal's Suspicious Order Monitoring Program.

11. My CV, which provides additional details about my professional experience, is attached as Appendix A. My billing rate is $675 per hour, and my compensation is not dependent on my opinions or the outcome of this litigation.

12. I have not testified as an expert at trial or by deposition in the last 4 years.

13. I have authored no publications in the last 10 years. However, I was part of the working group that led to the authoring of *The Prescription Opioid Epidemic: An Evidence-Based Approach*, Johns Hopkins Bloomberg School of Public Health (November 2015), https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

II. ASSIGNMENT

14. I have been retained by Zuckerman Spaeder LLP, on behalf of CVS Indiana, L.L.C. and CVS Rx Services, Inc. ("CVS") to serve as an expert witness in *County of Cuyahoga v. Purdue Pharma L.P.*, No. 17-OP-45004 and *County of Summit v. Purdue Pharma L.P.*, No. 18-OP-45090. I understand that Summit and Cuyahoga counties have sued CVS and that they allege that "various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market."[1] CVS Indiana, L.L.C. operates an Indianapolis, Indiana distribution center and CVS Rx Services, Inc. operates a Chemung, New York distribution center, and both are licensed to distribute Schedule III-V controlled substances in Ohio.[2] I understand that neither company is sued for dispensing (filling prescriptions).[3]

15. I have relied on my professional experience and considered a number of depositions and documents produced in this case in forming my opinions. A list of the materials I considered is attached as Appendix B. I also considered information provided in conversations with CVS employees identified in this report.

[1] Second Corrected Amended Complaint, *County of Summit, Ohio v. Purdue Pharma L.P.*, No. 18-OP-45090 (N.D. Ohio), ECF No. 514, ¶ 9.

[2] CVS Indiana L.L.C. (Indianapolis, Indiana), License No. 011648300, Board of Pharmacy, Wholesaler – Category 3, eLicense Ohio, https://elicense.ohio.gov/oh_verifylicensedetails?pid=a0Rt0000000rvcuEAA; CVS Pharmacy Distribution Center (Chemung, NY), License No. 012395150, Board of Pharmacy, Wholesaler - Category 3, eLicense Ohio, https://elicense.ohio.gov/oh_verifylicensedetails?pid=a0Rt0000001EL1XEAW.

[3] Opinion and Order on Motions to Dismiss, *County of Summit. v. Purdue Pharma L.P.*, No. 18-OP-45090 (Dec. 19, 2018 N.D. Ohio), ECF No. 1203, p. 2 ("The Court understands that Plaintiffs have disclaimed any cause of action against Retail Pharmacies in their capacity as retailers or dispensers of opioids[.]").

III. SUMMARY OF OPINIONS

16. I conclude the following:

a. CVS's suspicious order monitoring program complied with DEA regulations and was reasonable.

b. DEA does not require a registrant to have any particular system, as long as the system it chooses complies with the regulations.

c. Identifying suspicious orders is a subjective inquiry.

d. A suspicious order does not necessarily lead to diversion or harm.

e. Orders reflecting an increase in prescriptions written by legitimate prescribers are not suspicious.

f. It is reasonable that CVS did not discover any suspicious orders in Summit or Cuyahoga counties and therefore did not report any.

g. CVS was not a cause of an opioid epidemic in Cuyahoga and Summit counties.

h. Opinions of Plaintiffs' experts McCann, Whitelaw, and Rafalski are flawed.

IV. BACKGROUND

17. When people think of CVS they think of pharmacies. But no CVS pharmacy is sued in this lawsuit. The companies sued here, CVS Indiana, L.L.C. and CVS Rx Services, Inc., are distributors. These companies distribute products to CVS stores ranging from candy to paper towels to shampoo. They distribute controlled and non-controlled substances to these stores as well, where they can be dispensed to patients by CVS pharmacists pursuant to prescriptions written by doctors or other medical practitioners.

18. The CSA and its implementing regulations govern, among other things, the procurement, manufacturing, distribution, prescribing, dispensing, and disposal of controlled substances. As a general matter, distributors under the CSA transfer controlled substances from manufacturers to pharmacies or other dispensers.[4] Distributors do not dispense controlled substances to patients.

19. The CSA authorizes the Attorney General, whose authority has been delegated to DEA, to register distributors.[5] Any entity that seeks to distribute controlled substances must obtain a registration from DEA.[6] DEA must grant a distributor's application for a registration "unless [it] determines that the issuance of such registration is inconsistent with the public interest."[7] DEA may also revoke a distributor's registration if the distributor has "committed such acts" as would render its continued registration "inconsistent with the public interest."[8] DEA must consider several factors when determining whether the public interest requirement is met, including the "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[9]

20. DEA regulations require distributors to monitor orders for controlled substances placed with them by their customers. CVS's only customers are its pharmacies. The regulations provide that distributors must "design and operate a system to disclose to the registrant

[4] Distributors also may distribute controlled substances to other distributors.

[5] 28 C.F.R. § 0.100(b).

[6] 21 U.S.C. § 822, 823.

[7] 21 U.S.C. § 823(b), (e).

[8] 21 U.S.C. § 824(a)(4).

[9] 21 U.S.C. §823(b)(1), (e)(1).

suspicious orders of controlled substances."[10] "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[11] Suspicious orders, "when discovered," must be reported to DEA.[12] This regulation, as it pertains to CVS, regulates the transaction between the distributor and pharmacy. A separate regulation regulates the transaction between the pharmacist and the patient.[13]

21. DEA conducts periodic inspections of distribution centers that distribute controlled substances.[14] Distributors are required to report to DEA shipments of hydrocodone combination products ("HCPs") and other ARCOS-reportable controlled substances through the ARCOS database that is reviewed and analyzed by DEA.[15] DEA can initiate investigations independent and outside of the inspection process based on its analysis of ARCOS data. Like DEA, the Ohio Board of Pharmacy has the authority to conduct inspections of distributors[16], and distributors are required to report shipments of hydrocodone combination products to the Board of Pharmacy.[17] DEA has the ability to initiate a variety of actions when a registrant is not in compliance with DEA regulations.

22. DEA's administrative actions range from a letter of admonition ("LOA"), to a memorandum of agreement, to an order to show cause, to an immediate suspension order. DEA in conjunction with U.S. Attorney's Offices also can bring civil and criminal actions against distributors of controlled substances. An LOA is the least serious administrative action available to DEA, and it is less serious than actions for civil or criminal penalties.

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[10] 21 C.F.R. § 1301.74(b).

[11] 21 C.F.R. § 1301.74(b).

[12] 21 C.F.R. § 1301.74(b); Deposition of Joseph Rannazzisi, p. 307:2-3 ("A suspicious order report is one that is done when discovered.").

[13] 21 C.F.R. § 1306.04(a).

[14] 21 U.S.C. § 880.

[15] 21 C.F.R. § 1304.33.

[16] Ohio Admin. Code 4729-9-16(L)(1) (2006).

[17] Ohio Admin. Code 4729-37-03(B) (2006); Ohio Admin. Code 4729-37-03(C) (2011).

23. After an initial pre-registration inspection, distributors were typically inspected by DEA field offices every two to three years, or as deemed necessary. These inspections consisted of a broad-based review of the registrant's compliance with the CSA and its implementing regulations. Suspicious order monitoring ("SOM") is part of a distributor's regulatory responsibilities, and DEA would evaluate a distributor's suspicious order monitoring program as part of its routine inspections. Diversion investigators conduct these inspections. At the onset of the inspection, the investigators will present a notice of inspection for the registrant to sign, which authorizes the investigators to conduct the inspection. During the inspection, the investigators would, among other things, tour the distribution facility, review various documents and interview employees. After DEA completes an inspection, it may verbally indicate that the registrant passed the inspection, or it may follow up on the inspection with other forms of communication (i.e. letter, email, or telephone call). Typically, if DEA identified any areas of concern during an inspection, investigators would inform the registrant during the inspection as well as on the last day of the inspection.

V. OPINIONS

A. No Particular SOM System Is Required.

24. As stated above, the SOM regulation requires that distributors "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[18] The regulation does not specify any particular system. Likewise, DEA does not require a registrant to have any particular system, as long as it has a system that complies with the regulations.[19] A compliant suspicious order monitoring system may be manual. It also may have a computerized component, but that is not necessary.[20] A distributor has the discretion needed to design a system that fits its business.[21]

[18] 21 C.F.R. § 1301.74(b).

[19] Deposition of Thomas Prevoznik, p. 180:7-11 ("Q. And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A. Correct.").

[20] Deposition of Thomas Prevoznik, p. 180:12-15 ("Q. Does it matter to the DEA whether a registrant reviews orders manually or uses an automated system? A. No, it doesn't matter.").

[21] Deposition of Joseph Rannazzisi, pp. 315:24-316:12 ("And there was not any sort of guidance or checklist that were provided by DEA to registrants as to what was required to be in a suspicious order monitoring system, correct? . . . A. The regulation stands on its own. I believe the regulation says, the registrant shall design and

B. Identifying Suspicious Orders Is Subjective.

25. The SOM regulation states: "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[22] DEA regulations provide no guidance about what constitutes "orders of unusual size," "orders deviating substantially from a normal pattern," or "orders of unusual frequency" and what might render such orders suspicious. The determination therefore requires the professional judgment of the persons designing and/or operating the system. For instance, an order from a large pharmacy may not appear to be unusual, but the same size order from a small pharmacy may appear unusual. Determining whether an order is suspicious requires an evaluation of the order. Even if an order is unusually large, it "could perhaps be explained by nonsuspicious reasons" with due diligence.[23] An order of unusual size is not necessarily suspicious.[24]

26. One person could look at an order for controlled substances and reasonably conclude the order is not suspicious, while another person could look at the same order and reasonably conclude that order is suspicious.[25] DEA field offices and investigators across the country differed in how and whether they determined that certain orders were suspicious.

C. A Suspicious Order Does Not Necessarily Lead to Diversion or Harm.

27. Diversion occurs if a controlled substance flows "into other than legitimate medical, scientific, and industrial channels."[26] There are several ways a controlled substance can be diverted. By way of example, diversion can result from drug trafficking organizations or rogue pain clinics. Other examples include theft by a pharmacist or other pharmacy employee, theft of a controlled substance by a family member or friend, doctor shopping where someone visits

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operate a system that identifies and reports suspicious orders. Again, it's a business decision based on what the registrant's needs are and the Drug Enforcement Administration does not tell a registrant what that specific system should look like.").

[22] 21 C.F.R. § 1301.74(b).

[23] Deposition of Joseph Rannazzisi, p. 261:23-25.

[24] Deposition of Demetra Ashley, p. 147:8-11 ("Q. Based on your experience, would you agree that there might be situations where an order is of an unusual size, but the order is not suspicious? A. Yes.").

[25] Deposition of Thomas Prevoznik, p. 183:1-12 ("Q. Well, what I mean is that you and I looking at the same data, sometimes, not always, may come to different conclusions, as to whether an order is suspicious. Is that possible? . . . A. That is possible.").

[26] 21 U.S.C. § 823(b)(1), (e)(1).

multiple doctors to obtain prescriptions, obtaining prescriptions based on false pretenses, prescription forgeries where someone alters or creates a prescription to obtain a controlled substance, robberies of controlled substances while they are in transit or at a pharmacy, or end user misuse where a patient consumes a controlled substance for other than a legitimate medical purpose.

28. If a suspicious order is discovered by a registrant and is not reported to DEA, the SOM regulation is violated. However, it does not mean that any pills from the shipment will be diverted, misused or abused, or cause harm to the community.[27] For example, even if an order is unusually large and it is deemed suspicious by a registrant, the pharmacy may use every pill in the order to fill legitimate prescriptions. Without conducting a diversion investigation, it is not possible to determine whether pills from a suspicious order, or any other order, have been diverted or caused harm.

29. To properly determine whether pills from a suspicious order have been diverted or caused harm, an investigator would need to conduct an investigation. This investigation might include visiting the pharmacy, interviewing pharmacists, doctors, or other witnesses, reviewing prescriptions and medical records, reviewing financial records, or reviewing video surveillance, to name a few.

D. Orders Reflecting an Increase in Prescriptions Written by Legitimate Prescribers Are Not Suspicious.

30. The purpose of suspicious order monitoring is not to halt or limit the number of prescriptions being written in good faith by legitimate medical practitioners for any controlled substance. Plaintiffs' experts state that the number of prescriptions for opioid medications increased substantially.[28] One of Plaintiffs' experts states: "Available data indicate that prescribing of opioids increased across many specialties in medicine, and while some specialties of medicine have a more concentrated prescription practice for opioids (e.g., pain, anesthesia,

[27] Deposition of Thomas Prevoznik, p. 309:4-6 ("Q. Not every suspicious order leads to diversion, correct? A. Correct.").

[28] Expert Report of Anna Lembke, p. 10 ("Opioid prescribing tripled between the 1990's and 2012."); Expert Report of Katherine Keyes, p. 10 ("(ARCOS), which tracks prescription distribution and sales, indicate that prescription opioids were dispensed at a range of 96 mg per person in 1997, and increased to 700 mg per person by 2007 (>600% increase).").

and physical therapy), general practitioners in family and internal medicine dispenses the greater number of opioids, widespread across geographic areas of the US. This indicates that opioid prescriptions increased across many sectors, and across clinical practice areas."[29] It was not the role of any suspicious order monitoring program to stop this trend. It is appropriate for a distributor to fill a steady increase in orders that result from an increasing volume of prescriptions written in good faith by medical practitioners.[30]

E. CVS's Suspicious Ordering Monitoring Program Complied with the SOM Regulation and Was Reasonable.

31. In my opinion, CVS's suspicious order monitoring program complied with DEA regulations and was reasonable. My opinion is based on: (1) the regulatory history of the CVS distribution centers from 2006 to 2014; and (2) my review of CVS's controls in place from 2006 to 2014.

1. The Regulatory History of the CVS Distribution Centers

a. Indianapolis Distribution Center

32. The CVS Indianapolis, Indiana distribution center held a DEA certificate of registration to distribute Schedule III-V controlled substances. It operates as CVS Indiana, L.L.C. Between 2006 and the present, on an annual basis, DEA renewed CVS Indiana's certification of registration.[31] Additionally, between 2006 and 2014, DEA conducted three routine inspections of CVS's Indianapolis distribution center.

[29] Expert Report of Katherine Keyes, p. 18.

[30] The Prescription Opioid Epidemic: An Evidence-Based Approach, Johns Hopkins Bloomberg School of Public Health (November 2015), https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf, p. 36 ("Although prescription drug abuse is a complex, multi-faceted issue, the data strongly indicate that the vast majority of prescription drugs that are abused come from legitimate prescriptions."); Deposition of Joseph Rannazzisi, p. 192:6-8 ("I think that, if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing.").

[31] Indianapolis DEA Registration Certificates: CVS-MDLT1-000000265; CVS-MDLT1-000000259; CVS-MDLT1-000000251; CVS-MDLT1-000127089; CVS-MDLT1-000000250; CVS-MDLT1-000000240; CVS-MDLT1-000000225; CVS-MDLT1-000000226; CVS-MDLT1-000000214; CVS-MDLT1-000000065; CVS-MDLT1-000000050; CVS-MDLT1-000000031; CVS-MDLT1-000000018; CVS-MDLT1-000000006; Interview with Linda Cimbron, Director of Licensing; DEA must grant a distributor's application for a registration "unless [it] determines that the issuance of such registration is inconsistent with the public interest." 21 U.S.C. § 823(b), (e).

33. DEA inspected the Indianapolis distribution center on August 28, 2006.[32] There were no findings related to this inspection.[33] This meant that there were no issues with CVS's suspicious order monitoring program, or any other DEA regulatory requirements.

34. DEA next inspected the Indianapolis distribution center in August and September 2010.[34] As a result of the inspection, the DEA issued an LOA for "violations of the record keeping requirements under the Controlled Substances Act" on November 18, 2010.[35] This meant that there were no issues with CVS's suspicious order monitoring program.

35. DEA next inspected the Indianapolis distribution center in August 2013.[36] More than two years and four months later, on December 31, 2015, DEA issued an LOA stating "CVS failed to detect orders that should have been identified as suspicious for retail locations in Vincennes and Kokomo, Indiana."[37] The LOA did not state that CVS should have identified as suspicious any orders from pharmacies in Cuyahoga and Summit counties.

36. Moreover, in my opinion, the LOA was not based on a genuine concern about CVS's suspicious order monitoring system. DEA waited over two years to issue the LOA after it conducted the inspection. DEA typically issued LOAs within two to twelve weeks of the completion of an inspection. If DEA had meaningful concerns about CVS's suspicious order monitoring system, it would not have waited so long. In my experience, DEA promptly brings

[32] CVS-MDLT1-000010556 (DEA Notice of Inspection, August 28, 2006).

[33] Conversation with Gary Millikan, Retired Operations Manager, Indianapolis Distribution Center; Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[34] CVS-MDLT1-000061133; CVS-MDLT1-000057792 (CVS Notes from 2010 Inspection).

[35] CVS-MDLT1-000020423 (November 18, 2010 LOA) ("1. Failure to report to the DEA ARCOS Unit controlled substance receipt transactions as required by Title 21, Code of Federal Regulations, Sections 1304.33(e), and Title 21, United States Code, Section 827(d) in violation of 21 U.S.C. §842 (a)(5). 2. Failure to report to the DEA ARCOS Unit the correct date of controlled substance distributions as required by 21 CFR § 1304.33(e) and 21 U.S.C. § 827(d), in violation of 21 U.S.C. § 842(a)(5). 3. Failure to keep complete and accurate records as required by 21 CFR § 1304.21(a) and 1304.22(b) and 21 U.S.C. §827(b), in violation of 21 US.C. § 842(a)(5).").

[36] CVS-MDLT1-000031511 (CVS Notes from August 2013 DEA Inspection).

[37] CVS-MDLT1-000104851 (December 31, 2015 LOA) ("1. Failure to design and maintain a system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Title 21 United States Code (USC) 821, Title 21 USC 823(e)(1), and Title 21 Code of Federal Regulations (CFR) 1301.74(b) in violation of Title 21 USC 842(a)(5) in that CVS failed to detect orders that should have been identified as suspicious for retail locations in Vincennes and Kokomo Indiana. 2. Failure to maintain an accurate biennial inventory as required by Title 21 USC 827(a) and Title 21 CFR 1304.11(a) in violation of Title 21 USC 842(a)(5) in that for Clonazepam 1mg the summary page indicated one value while the supporting worksheets indicated another.").

administrative actions if it has serious concerns with a registrant's compliance with DEA regulations. The fact DEA not only waited more than 28 months before issuing the LOA, but that it also issued it on the last day of the year in 2015 shows that a DEA official issued the LOA for statistical reasons. Additionally, in 2013, DEA would have taken an administrative action more severe than an LOA if it believed a distribution center was failing to detect suspicious orders. As stated above, an LOA is the least serious administrative action available to DEA.

b. Chemung Distribution Center

37. CVS's Chemung, New York distribution center opened in 2011.[38] It operates as CVS Rx Services, Inc., d/b/a CVS Pharmacy Distribution Center.[39] DEA conducted a pre-registration inspection in April 2011.[40] On June 28, 2011, DEA granted the Chemung distribution center a DEA certificate of registration to distribute Schedule III-V controlled substances.[41] DEA conducted a routine inspection of the Chemung distribution center on June 17th, 19th, and 20th, 2013.[42] Between 2011 and the present, on an annual basis, DEA has renewed Chemung's certification of registration.[43] DEA has taken no administrative action against the Chemung distribution center.[44]

2. CVS Controls

a. 2006-2009

38. From 2006 to 2009, CVS had several controls in place relating to its distribution of controlled substances.

[38] Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[39] Chemung DEA Registration Certificates: CVS-MDLT1-000127091; CVS-MDLT1-000000117; CVS-MDLT1-000000102; CVS-MDLT1-000000088; CVS-MDLT1-000000077; CVS-MDLT1-000127090; Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[40] CVS-MDLT1-000123069 (CVS Official Government Agency Visits).

[41] CVS-MDLT1-000023148 (June 28, 2011 DEA Registration Certificate).

[42] CVS-MDLT1-000123069 (CVS Official Government Agency Visits).

[43] Chemung DEA Registration Certificates: CVS-MDLT1-000127091; CVS-MDLT1-000000117; CVS-MDLT1-000000102; CVS-MDLT1-000000088; CVS-MDLT1-000000077; CVS-MDLT1-000127090; Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[44] Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

39. First, CVS distributed only to CVS pharmacies.[45] It did not distribute to known sources of diversion, such as rogue pain clinics, rogue internet pharmacies, or dispensing practitioners.

40. Second, CVS did not distribute Schedule II controlled substances.[46] It did not therefore distribute controlled substances such as fentanyl, hydromorphone, oxycodone, or oxymorphone, which had the highest potential for abuse of any prescription drugs.[47] It distributed only Schedule III-V controlled substances, and it voluntarily stopped distributing hydrocodone combination products, which were Schedule III controlled substances, when DEA reclassified them to Schedule II in October 2014.[48]

41. Third, the Indianapolis distribution center, the only CVS defendant which distributed Schedule III-V controlled substances to pharmacies in Summit and Cuyahoga counties during this time period, had a manual system for reviewing orders of controlled substances. Employees who picked and packed or checked those orders were responsible for bringing any potentially unusual orders to the attention of their supervisors. Ellen Wilson, who picked and packed orders in the controlled substances cage for over twenty years at the CVS Indiana distribution center, testified that she used her years of experience and her "gut feeling" to bring unusual orders to her supervisor's attention.[49] Each order was reviewed not only by a picker but also by a checker, so

[45] Deposition of Mark Vernazza, p. 56:10-13 (the two CVS defendants "only distributed controlled substances to CVS pharmacies, to the best of my corporate knowledge."); Expert Report of Sonya Kwon, pp. 7-9.

[46] Deposition of Mark Vernazza, p. 56:2-9 ("Both of the CVS entities named as defendants in this case are distributors of controlled substances. They are now, and have always been, only distributors of Schedule III through V controlled substances, and have never been distributors of Schedule II controlled substances."); Expert Report of Sonya Kwon, pp. 9-11.

[47] 21 U.S.C. § 812(b)(2) (defining Schedule II controlled substances as having "a high potential for abuse" and "a currently accepted medical use[.]").

[48] Expert Report of Sonya Kwon, p. 9-11.

[49] Deposition of Ellen Wilson, pp. 61:8-62:19; Deposition of Mark Nicastro, pp. 298:5-12; 300:18-22 ("They would -- they would go through and pick the orders and they would review the orders for anything of unusual size. These were our experts. They were in the cage every single day. They picked these orders every single day. And they are going to be the best -- have the most knowledge as to whether an order seems unusual size or pattern . . . We relied on them to use their experience to flag anything that looked suspicious to them, and they would -- they would escalate those to their pharmacy supervisor or manager, and they would take it from there."); Deposition of Gary Millikan, pp. 132:25-133:6 ("When you're there [as a picker and packer] and you're doing it, something just doesn't feel right sometimes. For example, you go to this one section and you -- in that number of stores you're picking today, you pick one and one and one and one, and you get an eight. Does eight concern you? Bring it up to us. Let's look into it.").

two persons in the controlled substances cage independently reviewed every order.[50] It was CVS policy to decline to ship any order, which was determined to be suspicious, and to report the order to DEA.[51] In my opinion, a manual system of this nature meets the requirements of 21 C.F.R. § 1301.74(b) and was reasonable.[52]

42. Fourth, CVS had in place a program through its pharmacy loss prevention department to monitor ordering patterns, among other things. The program was based on a monthly report called the Prescription Drug Monitoring Report ("PDMR"). This report was reviewed by personnel in the field called Regional Loss Prevention Managers ("RLPMs"), each of whom had responsibility for a particular geographic area. There were several RLPMs for the Cleveland and Akron areas. For pharmacies that were identified for review by a computerized system, based on the following information, the PDMR showed for the pharmacy the particular drug in question, the drug schedule, the number of dosage units received from CVS distribution centers, the number of dosage units received from any outside vendor, the number of dosage units dispensed, the difference between the dosage units received and the dosage units dispensed, any difference between expected inventory and the manual inventory reported by the pharmacy, and any manual changes made by the pharmacy to increase the size of the computer-generated order.

43. This information enabled RLPMs to identify potential concerns requiring further investigation relating to ordering patterns or possible diversion. The RLPMs would then conduct investigations as they saw fit, and to the extent they identified concerns they would address them in conjunction with the pharmacy manager (pharmacist in charge). Although the PDMRs were generated monthly and could not have been used to identify suspicious orders in real-time, they complimented the real-time suspicious order monitoring program by providing for a monthly

[50] Conversation with Ellen Wilson, Warehouse Employee, Indianapolis Distribution Center; Conversation with Gary Millikan, Retired Operations Manager, Indianapolis Distribution Center.

[51] "When CVS determines that an order for a controlled substance is suspicious, its policy is and has been to decline to ship the order and to report the order to the DEA." CVS's Written Responses to Topics 8, 9, 12, 13, and 14 of Plaintiffs' Amended Second Notice of Deposition Pursuant to Rule 30(b)(6) (Nov. 15, 2018) ¶ 14.

[52] Mr. Rafalski and Mr. Whitelaw criticize Ms. Wilson for relying on her "gut" instincts. Expert Report of James Rafalski, p. 105; Expert Report Seth Whitelaw, pp. 169-170. It is very reasonable for a warehouse employee to rely on her gut based on her knowledge and experience.

review of ordering patterns and by addressing circumstances of concern.[53] This was another effective control against diversion and another form of due diligence.

44. While the above controls are sufficient in and of themselves, I note that CVS's pharmacy business also had in place policies on the proper dispensing of controlled substances and assigned pharmacy supervisors to each pharmacy to promote conduct at the pharmacies consistent with the policies. Its policies stated that "[e]mployees are expected to fill and refill only legal and authorized prescriptions" and that "[t]he exercising of corresponding responsibility is especially important with regard to 'questionable' prescriptions for controlled drugs."[54] Pharmacy supervisors, who supervised pharmacy managers, were not on staff at a pharmacy and rather were assigned to oversee several pharmacies in a particular geographic area, were present in each pharmacy they supervised typically at least once a month (or more often as needed). Their job was to work with the pharmacists on overall compliance, patient needs, and pharmacy operations. This was in addition to the pharmacy manager (pharmacist in charge) in each of the pharmacies and to the RLPMs who also monitored the pharmacies.[55]

b. 2009 – Early 2014

45. From 2009 to early 2014, CVS kept in place the above controls related to its distribution of controlled substances and enhanced them by adding a computerized system to assist in identifying potentially suspicious orders and a process for manually reviewing the reports from that system. In the spring of 2008, CVS hired an outside consultant, Ronald Buzzeo, former

[53] Conversation with John Robinson, Director of Asset Protection; CVS-MDLT1-000068377 (May 29, 2007 PDMR Report).

[54] CVS-MDLT1-000055540 (December 21, 2004 Professional Practices Policy); CVS-MDLT1-000081559 (June 30, 2011 Suspected Fraudulent or Altered Prescriptions Policy) ("Employees should be constantly [on] alert for any potential indicators of diversion, including the use of fraudulent or altered prescriptions to obtain medications . . . If a pharmacist has a question about any aspect of a prescription, the pharmacist must not dispense until the legitimacy can be verified."); CVS-MDLT1-000081566 (January 4, 2012 Protocol for Dispensing Narcotic Drugs for Pain Treatment) (Pharmacists "should exercise particular caution before filling a prescription . . . from practitioners who prescribe the same medication in the same dosage amounts to most or all of their patients . . . from practitioners who you are aware do not take insurance or whose patients have insurance but always insist on paying cash for their prescriptions. . . from individuals who come to the pharmacy in groups to get narcotic prescriptions filled."); CVS-MDLT1-000081508 (February 22, 2012 Professional Standards Policy) ("Employees are expected to fill and refill only legal and authorized prescriptions. They are expected to uphold this legal and moral responsibility by keeping up to date on all State and Federal changes in pharmacy jurisprudence[.]").

[55] Deposition of Mark Vernazza, pp. 146:10-148:4; Conversation with Nicole Harrington, Senior Director of Pharmacy Services.

Deputy Director of DEA's Office of Diversion Control, and his company to design this computerized system.[56] Mr. Buzzeo was a very reasonable choice for this work. Mr. Buzzeo's company delivered the computerized SOM system in December 2008.[57]

46. The Buzzeo computerized system was put in place in the first part of 2009.[58] The system was based on an algorithm that relied on historical information and scored each order.[59] If a score exceeded a certain level, the order would appear on a daily item review report ("IRR") for a CVS analyst to review.[60] The system did not identify suspicious orders. Rather, it identified orders that "should be 'pended' to allow further investigation to determine whether the order is in fact a 'suspicious order' for reporting purposes."[61] In my opinion, this system complied with 21 C.F.R. § 1301.74(b) and was reasonable.[62]

47. The IRR identified information such as the drug ordered, the size of the order, the store that ordered it and information about order history.[63] Each item on the report was reviewed by CVS analysts.[64] The analysts testified that they understood the IRR at the time they reviewed it.[65] Reviewing the IRR in and of itself was a form of due diligence.[66]

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[56] CVS-MDLT1-000119208 (2008 Consulting Services Agreement) (CVS hired Mr. Buzzeo and his company to "customize a suspicious order monitor (SOM) statistical model for [CVS] using [Buzzeo's] Ph.D. statisticians and DEA consulting team.").

[57] CVS-MDLT1-000123386 (December 2008 Overview of Buzzeo SOM Model); CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[58] CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[59] CVS-MDLT1-000123386 (December 2008 Overview of Buzzeo SOM Model); CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[60] Deposition of Aaron Burtner, pp. 69:20-70:5 ("Q. Okay. And that Item Review Report was a result of the computer system going through its algorithm process to then cause certain orders to appear on that IRR report daily. Is that right? . . . A. That is my understanding."); Deposition of John Mortelliti, p. 40:7-9 ("Q. In addition to an IRR -- and this is a daily report, right? A. Yes.").

[61] CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[62] Dr. William Choi evaluated this system and determined that it was based on reasonable statistical methods. Expert Report of William Choi, pp. 3, 12.

[63] CVS-MDLT1-000010672 (August 30, 2013 IRR); Deposition of Aaron Burtner, p. 122:2-8 ("Q. And the [IRR] report identifies orders that are statistically significant or that vary from historical monthly trends based upon the previous six months as well as the current month. Correct? A. Yes.").

[64] Deposition of Aaron Burtner, pp. 521:20-522:3 ("To the best of your knowledge, did you and the SOM team, when you worked in SOM, review all of the orders flagged on an IRR . . . Q. -- on a daily basis? A. Yes. We reviewed every order on the IRR on a daily basis."); Deposition of Shauna Helfrich, p. 245:18-20. ("Q. Do you remember whether you reviewed all of the orders that CVS's system flagged? A. Yes."); Deposition of John

48. The analysts had the ability to conduct additional due diligence beyond the IRR, if they believed it was necessary, to come to a reasonable conclusion about whether the order was suspicious or not. They had access to other CVS resources, including loss prevention personnel, pharmacists from the store that placed the order[67], and other databases with pertinent information i.e. VIPER[68] and Microstrategy.[69] The analysts testified that they had the time and resources necessary to conduct their due diligence.[70]

Mortelliti, p. 54:6-17 ("What do you do with the hydrocodones that are flagged as of interest or potentially suspicious? A. Freeze the orders within the distribution centers. I would contact the field VIPER analyst in those areas. I would also contact the regional loss prevention managers for them to do an investigation. Q. And you did that in 2009 up to October of 2010 for every flagged hydrocodone order. Is that your testimony? A. Yes."); Deposition of Mark Vernazza, pp. 394:21-395:4 ("Q. And the IRR report is what's being reviewed every day to look for flagged orders so you can start to investigate, correct? . . . A. That's my understanding.").

[65] Deposition of Aaron Burtner, pp. 522:18-523:5 ("And during that same -- at that time, you also understood the information presented in the IRR? . . . Yes, at that time I understood the IRR Q. Including all the scores that appeared for each drug in the IRR? . . . A. Yes. I had a much better understanding of all of the data on the IRR at that time."); Deposition of Shauna Helfrich, p. 245:8-11. ("Q. Ms. Helfrich, do you recall whether at the time you were a SOM analyst you felt you understood the IRR? A. Yes.").

[66] Other than section 21 C.F.R. § 1301.74(a), the CSA and its implementing regulations do not dictate how to conduct due diligence. CVS satisfies the requirement in § 1301.74(a), through its internal mainframe, which only allows orders from pharmacies with active DEA registrations. Conversation with Linda Cimbron, Director of Licensing; Conversation with John Andrade, Senior Manager, Application Development, IS - Retail Systems-Logistics.

[67] Deposition of Shauna Helfrich, pp. 196:1-6 ("Q. Can we talk generically about what due diligence can be done to figure out whether or not a order is suspicious? So you can contact and speak to the pharmacist, correct? A. Yes.")

[68] VIPER, which was available throughout the Buzzeo era, provided information about the store's ordering history. Deposition of Kelly Baker, p. 136:4-8 (VIPER "lets you compare how many was shipped versus how many was dispensed[.]"); Deposition of Shauna Helfrich, p. 29:6-8 ("The Viper Report, as I can remember, gave me the balance on hand for that store for a particular drug[.]"); Deposition of Aaron Burtner, p. 380:12-15 ("Q. What this [VIPER PDMR] tells you is how much was shipped to the pharmacy and how much was dispensed from the pharmacy, correct? A. Correct.").

[69] Microstrategy, which became available to the analysts later, provided information about the pharmacy's dispensing. Deposition of Aaron Burtner, p. 380:7-12 (MicroStrategy had "dispensing history for a store and several data points related to the script that was filled, such as doctor, customer, payment method, how far the customer had driven from their home to the location[.]"); Deposition of Shauna Helfrich, p. 19:3-6 (Microstrategy had "the patient ID number, doctors, and PI number. Insurance, how the drug was paid for [and] [q]uantity of the drugs, dispense[d].").

[70] Deposition of Shauna Helfrich, p. 246:4-7 ("Q. When you were a SOM analyst, did you always conduct the due diligence that you believed was necessary? A. Yes."); Deposition of Kelly Baker, pp. 366:24-367:4 ("Q. Was there ever a time when you felt you did not have the resources or time to complete your job? A. That's kind of -- I think we had the resources I needed to do my job."); Deposition of Aaron Burtner, p. 522:12-16 (Q. And did you have access to all of the data and information that you thought was necessary to evaluate those orders? . . . A. Yes, I believe so.").

49. Notably, in August 2013, CVS hired Matthew C. Murphy, DEA's former head of Pharmaceutical Investigations and his company the Pharma Compliance Group, to assist its analysts with their suspicious order monitoring due diligence. Pharma Compliance continued to assist until early 2014.[71]

50. It was CVS policy not to ship an order listed on the IRR until or unless it was cleared and to report any suspicious orders, when discovered, to the DEA.[72] The SOM analysts testified that they were not aware of any suspicious orders that shipped.[73]

51. In March 2012, when this system was in operation, CVS "[a]s part of [its] efforts to continuously assess and enhance its controlled substances and listed chemical systems and processes . . . requested the assistance of the Drug and Chemical Advisory Group, LLC. (DCAG) in conducting an evaluation of its suspicious order monitoring (SOM) program[.]"[74] The evaluation was conducted by Terrance Woodworth. Mr. Woodworth was the former Deputy Director, DEA Office of Diversion Control.

52. As part of his evaluation, Mr. Woodworth spent three days at the distribution center where the SOM system was being managed, and he met with among others, two SOM analysts conducting the daily IRR review.[75] Mr. Woodworth concluded that CVS "has established an effective, centrally operated suspicious order monitoring program . . . and CVS continues to update and improve its SOM program."[76] He also concluded "that the overall approach is not focused on reviewing and rapidly releasing an order to ensure store delivery dates. The priority

[71] CVS-MDLT1-000104918 (August 2013 Pharma Compliance Group Engagement Letter); Deposition of Dean Vanelli, p. 235:16-238:6; Deposition of Kelly Baker, pp. 59:1-60:13; Deposition of Shauna Helfrich, p. 224:4-21.

[72] CVS-MDLT1-000109871 (February 29, 2012 Work Instruction Loss Prevention Analyst); CVS-MDLT1-000009812 (March 28, 2012 List 1 Chemicals (PSE, EPH) and Control Drug Policy & Procedure).

[73] Deposition of Shauna Helfrich, p. 248:9-11 ("Q. Did you ever let an order ship that you were concerned might be suspicious? A. No."); Deposition of Aaron Burtner, p. 523:20-24 ("Q. Okay. But you're not aware of any suspicious order that CVS shipped during your time working in SOM for CVS? . . . A. No, I am not.").

[74] CVS-MDLT1-000125136 (April 6, 2012 DCAG Report).

[75] CVS-MDLT1-000125136 (He "met with several key members of the CVS SOM team: Frank R. Devlin, Director Logistics Loss Prevention (Rhode Island), John Mortelliti, Logistics Regional Director, Loss Prevention (New Jersey), Pamela J. Hinkle, Senior Loss Prevention Manager, (Tennessee), Paul Lawson, Logistics Loss Prevention Analyst (Tennessee), Aaron J. Burtner, Logistics Loss Prevention Analyst (Indiana), Attorney Margaret P. Griffiths, (Illinois), and King & Spaulding Attorney Stephen P. Cummings (Georgia).").

[76] CVS-MDLT1-000125136 (April 6, 2012 DCAG Report).

clearly is to detect any problem or issue that indicates an order may not be valid or legitimate. The review and analysis of irregular orders are completed expeditiously; and while sales productivity, customer store and patient satisfaction are paramount, the foundation of the CVS SOM is ensuring the legitimacy of these transactions."[77]

53. This system was designed, evaluated, or assisted by three former high-ranking DEA officials from the Office of Diversion Control.[78] The selection of these individuals shows CVS's commitment to its suspicious order monitoring program.

c. Early 2014 – End of 2014

54. In early 2014, CVS replaced the Buzzeo system with a new computerized system to assist in identifying potentially suspicious orders. Like the Buzzeo system, this system operated in conjunction with controls discussed above in Section V.E.2.a. Even though this system has been in operation continuously through the present, CVS stopped distributing HCPs after September 2014. I travelled to CVS corporate headquarters in Woonsocket, Rhode Island to see the system in operation. While there, I sat with one of the analysts (Megan Matos) and the group supervisor (Annette Lamoureux) and observed their work in real-time.

55. The new system is based on a set of computerized tests that identifies orders for review. Some of the tests are based on size, some are based on frequency, and some are based on ordering pattern. The tests are run overnight against every order placed by a CVS pharmacy the preceding day, and the system identifies orders for review based on one or more of the tests. Every order that is identified is then held and placed in a queue for review.

56. Beginning in the early morning, CVS analysts begin their reviews by selecting an order from the queue. The analyst opens a file, which shows basic information about the order for review, such as the drug that was ordered, how much was ordered, the pharmacy it was ordered from, and the distribution center that would fill the order. The computer interface allows the analyst to link to more specific information. For example, the analyst can see information

[77] CVS-MDLT1-000125136 (April 6, 2012 DCAG Report).

[78] This system covered all of the CVS distribution centers that were registered to distribute Schedule III-V controlled substances. Other than the 2015 LOA issued to the Indianapolis distribution center discussed above, DEA never took any action against CVS based on this system. CVS-MDLT1-000123069 (CVS Official Government Agency Visits); Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

related to the relevant tests, the pharmacy, the order, the patient, the prescriber, cocktail information, and the method of payment. The analyst can supplement his or her review through additional information, such as a map showing what is in the vicinity of the pharmacy, a comparison of the amount of the drug ordered and the amount dispensed, the balance on hand for the particular drug at the pharmacy, and the distance the patient travelled. All of this information is accessible through each analyst's computer. When deemed necessary, an analyst may also call the pharmacy to ask any questions raised by his or her review.

57. Based on an analyst's review of this information, the analyst decides whether to clear the order or not. If the analyst is unable to resolve any questions about the order, the order continues to be held and is elevated for further review. The order is then either: (1) cleared as not suspicious; or (2) identified as suspicious, not shipped and reported to DEA.

58. In my opinion, this system complied with 21 C.F.R. § 1301.74(b) and was reasonable.

F. It is Reasonable that CVS Did Not Discover Any Suspicious Orders Placed by Pharmacies in Summit and Cuyahoga Counties.

59. DEA regulations require a system to disclose and report, when discovered, suspicious orders. However, this does not mean a customer will place a suspicious order.[79] If no suspicious orders are placed, there are none for the distributor to discover or report. Based on the circumstances here, it is reasonable in my opinion that CVS did not discover any suspicious orders placed by any of the CVS pharmacies in Cuyahoga and Summit counties and therefore did not report any.

60. First, CVS distributed only to CVS pharmacies.[80] It did not distribute to known sources of diversion, such as rogue pain clinics, rogue internet pharmacies, or dispensing practitioners. CVS therefore did not receive orders from these types of customers.

61. Second, CVS did not distribute any of the controlled substances that were considered to have the highest potential for abuse of any prescription drugs (Schedule II).[81] It did not

[79] 21 C.F.R. § 1301.74(b).

[80] Deposition of Mark Vernazza. p. 56:10-13 (the two CVS defendants "only distributed controlled substances to CVS pharmacies, to the best of my corporate knowledge."); Expert Report of Sonya Kwon, pp. 7-9.

distribute drugs like fentanyl, hydromorphone oxycodone, or oxymorphone. Of the controlled substances relevant to this lawsuit, CVS only distributed HCPs, which were Schedule III controlled substances until October 6, 2014, and voluntarily stopped distributing them when DEA reclassified them to Schedule II.[82] CVS only distributed about [redacted] of Morphine Milligram Equivalence ("MME") into Cuyahoga County and [redacted] of MMEs into Summit County from 2006 through CVS's last shipment of HCPs in September of 2014.[83]

62. Third, as required by ARCOS, CVS reported to DEA all shipments of hydrocodone combination products to its pharmacies in Cuyahoga and Summit counties.[84] DEA never indicated to CVS that any of the orders placed by its pharmacies in Cuyahoga and Summit counties should have been discovered as suspicious and never brought any orders to show cause, immediate suspension orders, or civil or criminal actions based on these shipments.[85] The Ohio Board of Pharmacy also regulated the distribution of controlled substances within the state of Ohio[86], and also required distributors to report all shipments of HCPs.[87] Like DEA, the Ohio Board of Pharmacy never indicated to CVS that any of the orders placed by its pharmacies in

[81] Deposition of Mark Vernazza. p. 56:2-9 ("Both of the CVS entities named as defendants in this case are distributors of controlled substances. They are now, and have always been, only distributors of Schedule III through V controlled substances, and have never been distributors of Schedule II controlled substances."); 21 U.S.C. § 812(b)(2) (defining Schedule II controlled substances as having "a high potential for abuse" and "a currently accepted medical use[.]"); Expert Report of Sonya Kwon, pp. 9-11.

[82] Expert Report of Sonya Kwon, pp. 9-11.

[83] Expert Report of Sonya Kwon, pp. 12-14.

[84] 21 C.F.R. § 1304.33; Expert Report of Sonya Kwon, p. 6 (stating "I compared the summaries of HCP transactions and total weight from the ARCOS and CVS distribution data described in the preceding paragraphs. I determined both datasets capture the same shipments with similar number of packages and active ingredient weights.").

[85] Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[86] Ohio Admin. Code 4729:9-16(H)(1)(e) (2006) ("A system of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse (i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns. (ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.").

[87] Ohio Admin. Code 4729-37-03(B) (2006); Ohio Admin. Code 4729-37-03(C) (2011).

Cuyahoga and Summit counties were suspicious and never took any action against CVS for failing to report or discover suspicious orders.[88]

63. Fourth, from 2006 to 2014, neither the Ohio Board of Pharmacy nor DEA suspended or revoked the license of any of the sixty-nine CVS pharmacies in Summit or Cuyahoga counties.[89] Both the Ohio Board of Pharmacy and the DEA had the authority to conduct periodic inspections of pharmacies.[90] In my experience, the Board of Pharmacy and DEA would have inspected CVS pharmacies many times during this period. In addition, the Ohio Board of Pharmacy had access to the Ohio Automated Rx Reporting System ("OARRS"), which included data on controlled substance prescriptions filled by these pharmacies.[91]

64. Fifth, CVS pharmacies in Summit and Cuyahoga counties, to which CVS was distributing HCPs, were legitimate, everyday, full-service pharmacies placing orders necessary to address the full range of medical needs of their customers. This is shown by the small proportion of controlled substances to non-controlled substances distributed to its pharmacies in Summit and Cuyahoga counties.[92] From 2006 through September 2014, "[c]ontrolled substances represent less than [redacted] of shipments, less than [redacted] of packages, and less than [redacted] of dosage units shipped to CVS pharmacies in Cuyahoga and Summit counties by CVS distribution centers and Cardinal Health combined[.]"[93]

[88] Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[89] Conversation with Linda Cimbron, Director of Licensing; Expert Report of Sonya Kwon, p. 7 fn.23 ("There are 69 CVS stores in the distribution data with shipments between 1/1/2006 and 9/30/2014.").

[90] Ohio Admin. Code 4729-9-16(L)(1) (2006); 21 U.S.C. § 880.

[91] Ohio Admin. Code 4729-37-03(A) (2006); Ohio Admin. Code 4729-37-03(B) (2011).

[92] Expert Report of Sonya Kwon, pp. 16-24.

[93] Expert Report of Sonya Kwon, p. 21. Broken down by store during this time period, the percentage of controlled substances by number of shipments from CVS and Cardinal Health ranged from [redacted] to [redacted]; the percentage of controlled substances by number of packages shipped from CVS and Cardinal Health ranged from [redacted] to [redacted]; the percentage of controlled substances by number of dosage units shipped from CVS and Cardinal Health ranged from [redacted] to [redacted]. Expert Report of Sonya Kwon, Exhibit 14C, 15C, 16C. Joseph Rannazzisi, the former Deputy Assistant Administer, Office of Diversion Control testified that "for the most part, pharmacies generally follow a pattern of ordering for controlled substances and depending on what we have read, it could be anywhere as low as 9 percent to up to 12 or 13 percent as the average. So it is a red flag when a pharmacy is ordering, you know, 40, 50 percent of their drugs has controlled substances[.]" Joseph Rannazzisi. pp, 453:21-454:3.

G. CVS Was Not a Cause of An Opioid Epidemic in Cuyahoga and Summit Counties.

65. For the same reasons stated in Section V.F, it is my opinion that CVS did not cause an opioid epidemic in Summit and Cuyahoga counties.

H. The Opinions of Plaintiffs' Experts Are Flawed.

1. Rafalski and Whitelaw

a. Written Policies

66. Plaintiffs' experts criticize CVS for its lack of written policies prior to 2010 related to suspicious order monitoring.[94] Neither the CSA nor DEA regulations require a registrant to have written standard operating procedures.[95] What is important is what is done to discover any suspicious orders and how they are handled upon discovery.

67. Mr. Whitelaw also criticizes CVS for revising its policies too often after 2010 and for being vague.[96] It is very reasonable to revise corporate policies frequently. Moreover, CVS policies clearly set forth the key elements of the program: review the IRR, conduct any further due diligence as necessary, and stop any shipments discovered to be suspicious and report them to DEA.[97]

b. Loss of Order History

68. Plaintiffs' experts criticize the Buzzeo system for a glitch in 2010 caused by changes to drug names or titles (for example when "Hydro 5 mg" is changed to "hydro mg 5").[98] In my opinion, Plaintiffs' criticisms are unfounded. This glitch resulted in certain order history not populating in the IRR. However, the person in charge of the IRR review at the time, John Mortelliti, testified that when this occurred, he still was able to conduct the necessary review of

[94] Expert Report of James Rafalski, p. 96; Expert Report of Seth Whitelaw, pp. 171-172.

[95] Deposition of Thomas Prevoznik, pp. 358:21-359:1 ("Q. Does it say anywhere in the relevant regulations that registrants are required to have a written policy with respect to suspicious order monitoring? A. No.").

[96] Expert Report of Seth Whitelaw, pp. 171-172.

[97] CVS-MDLT1-000008964 (August 25, 2010 SOP); CVS-MDLT1-000009033 (November 29, 2010 SOP); CVS-MDLT1-000008898 (March 11, 2011 SOP); CVS-MDLT1-000003177 (May 6, 2011 SOP); CVS-MDLT1-000008506 (November 8, 2011 SOP); CVS-MDLT1-000008572 (April 18, 2013 SOP).

[98] Deposition of John Mortelliti, p. 154:6-7.

the orders and obtain the information he needed by other means.[99] At the same time, Mr. Mortelliti addressed this glitch by submitting an internal request to fix it. The request stated: "DEA expects CVS to prevent suspicious orders from being filled out of our DC's. The current IRR does not provide the proper information to meet the DEA's needs. We need control drugs to be monitored by 'active ingredient.' Currently the control drugs are monitored by item. The IRR loses all order history when the info on the item changes causing CVS to be non compliant with DEA expectations."[100] When asked about this document, Mr. Mortelliti testified: "we were compliant. I worded this to get it pushed through the system."[101]

c. Change in Score

69. Plaintiffs' experts criticize CVS for changing the score for which an order appeared on the IRR from .15 and .65.[102] It is perfectly reasonable for a registrant to make adjustments to its system, especially when the system was created by outside consultants and was in its initial implementation period. The record demonstrates that the reason for adjusting the score was to reduce the number of false positives[103] and that Mr. Mortelliti advised Buzzeo of it.[104] In my opinion, this not only was reasonable, it was appropriate.[105]

d. Outside Vendor Orders

70. Plaintiffs' experts criticize CVS because they say that the SOM system did not consider outside vendor orders.[106] I disagree with this criticism. As stated above in Section V.E.2.a, the PDMR included outside vendor orders for use by the RLPMs to evaluate the ordering patterns of particular pharmacies. From at least 2012, SOM analysts also had access to a database that

[99] Deposition of John Mortelliti, pp. 145:21-24; 152:6-11.

[100] CVS-MDLT1-000034172; CVS-MDLT1-000034175 (October 7, 2010 Email from Gary Misiaszek to Ellen Demetrius with attached Business Idea Description).

[101] Deposition of John Mortelliti, p. 135:9-10.

[102] Expert Report of Seth Whitelaw, pp. 175-176; Expert Report of James Rafalski, p. 107.

[103] Deposition of John Mortelliti, p. 287:15-19 ("Q. Okay. What you were fixing to do -- what you were intending to do, I should say, with this algorithm was you wanted to tweak it up, right? A. I wanted to eliminate false positives.").

[104] Deposition of John Mortelliti, p. 284:5-7 ("We had conversations with the people who built the algorithm, and they assured us that we were within line.").

[105] Dr. William Choi testified that based on his expertise the score change was appropriate as a statistical matter. Deposition of William Choi, pp. 140:20-143:19; Expert Report of William Choi, p. 23.

[106] Expert Report of James Rafalski, p. 106; Expert Report of Seth Whitelaw, p. 182.

contained outside vendor orders.[107] In addition, on average between January 2006 and September 2014, only 5.7% of the dosage units of HCPs shipped to CVS pharmacies in Summit and Cuyahoga counties were from outside vendors.[108] These pharmacies ordered a much larger percentage of non-controlled substances from outside vendors (13.9% of non-controlled from outside vendors versus 86.1% of non-controlled from CVS distribution centers).[109]

71. There were very legitimate reasons why an everyday, full service CVS pharmacy would place orders for controlled or non-controlled substances from an outside vendor. CVS distribution centers generally shipped to each CVS pharmacy once a week.[110] If a pharmacy were to run out of a particular product before it received its weekly shipment, or if the CVS distribution center was out of stock of a particular product, a pharmacy may need to order from an outside vendor to ensure it had sufficient inventory to meet the needs of patients.[111]

e. Document Retention

72. Mr. Rafalski incorrectly states that registrants are required to maintain due diligence records forever.[112] To the extent the CSA or its implementing regulations require a record to be maintained, 21 C.F.R. § 1304.04(a) establishes a two-year retention period. While some states may require a longer retention period and registrants in those states would be required to follow that longer retention period, I am not aware of any state that requires registrants to maintain due diligence records forever.

f. Conflict of Interest

73. Mr. Whitelaw claims that it was a conflict of interest for a company such as CVS to distribute to its own pharmacies.[113] This is not so. Both business activities were approved and

[107] Deposition of Aaron Burtner, p. 284:6-13 ("Q. So are you looking at outside vendor orders on the IRR? A. No, we were not. Q. Okay. The only way you'd know that is if you called the store and asked them, right? A. No. We had access to that data we could pull from a different tool.").

[108] Expert Report of Sonya Kwon, pp. 27-28

[109] Expert Report of Sonya Kwon, p. 29

[110] Deposition of Mark Nicastro, p. 305:20-21 ("our stores order once a week with the exception of a handful of stores that order twice a week."); Conversation with Nancy Mitchner, Staff Pharmacist (Store #4800).

[111] Conversation with Nancy Mitchner, Staff Pharmacist (Store #4800).

[112] Deposition of James Rafalski, pp. 125-126; 171-172.

[113] Expert Report of Seth Whitelaw, p. 46.

licensed by federal and state regulators, and there is nothing improper about performing both roles.

g. Stores 3322 and 4800

74. Plaintiffs' experts criticize two CVS stores for ordering and receiving high volumes of prescription opioids, without considering the facts and circumstances of the stores.[114] Plaintiffs' experts are wrong to rely on the volume of orders alone. The first store, at 2007 Brookpark Road in Parma (Store #3322), is one of the largest volume CVS pharmacies in the Cleveland area, if not the largest. It is located in a high traffic area right off of 480, an interstate that runs through the Cleveland area, and Route 176. Since at least 2006, it has been a 24 hour pharmacy. It is in a densely populated area, on the border of Parma and Cleveland, and draws from both cities and the surrounding area. There are several hospitals nearby, including Metro Health, Parma Hospital and St. Vincent's Hospital. Nearly 80% of its orders (by dosage unit) from 2006 to 2014 were for non-controlled substances.[115]

75. The second store, at 590 East Market Street in Akron (Store #4800) is situated on a main bus route and located right across the street from Suma Akron City Hospital and within approximately two miles of Cleveland Clinic Akron General and Akron Children's Hospital. Since at least 2006, it has been a 24 hour pharmacy. It is in a high foot traffic area, the same area as the University of Akron and borders a residential community. More than 80% of its orders (by dosage unit) from 2006 to 2014 were for non-controlled substances.[116]

h. Settlements

76. Rafalski and Whitelaw cite prior settlements between DEA and CVS.[117] For the reasons stated above, and due to the nature of the settlements and the scope of CVS's business, they do not alter my opinions.

[114] Expert Report of Seth Whitelaw, p. 51-52; Expert Report of James Rafalski, p. 53.

[115] Conversation with Christa Altobelli, District Leader; Conversation with Nate Reese, Pharmacy Manager (Store #3322); Expert Report of Sonya Kwon, Exhibit 16C.

[116] Conversation with Nancy Mitchner, Staff Pharmacist (Store #4800); Expert Report of Sonya Kwon, Exhibit 16C.

[117] Expert Report of Seth Whitelaw, pp. 162-163; Expert Report of James Rafalski, pp. 101-104.

2. McCann

77. Plaintiffs identify "excessive" orders through economic analysis presented in the report of Dr. McCann.[118] Solely running mathematical formulas against a distributor's orders from five or more years ago with no consideration of the unique facts and circumstances surrounding the orders or the pharmacies that placed them is insufficient to identify suspicious orders or to call into question real-time professional judgments made at the time. As explained above, the suspicious order inquiry is subjective and order-specific. To the extent Mr. Rafalski concludes that Dr. McCann's formulas are sufficient to identify suspicious order, he is incorrect.[119]

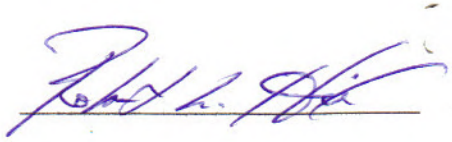
78. Plaintiffs' analysis is further unreasonable in that it flags as suspicious "every subsequent" order placed by a pharmacy after the first order that Plaintiffs identified as suspicious.[120] But because Plaintiffs have not established that the first order is in fact suspicious through an investigation of the facts and circumstances surrounding the order and the pharmacy that placed it, they cannot use it to tag even one subsequent order as suspicious, let alone "every subsequent" order. Moreover, even if Plaintiffs had established through a hypothetical, retrospective investigation that the first order should have been discovered as suspicious, it does not automatically follow that each and every subsequent order was suspicious. Suspicious orders can result from one-time events and as stated above do not necessarily lead to diversion or harm. To determine that any subsequent order is suspicious, a real time investigation of the facts and circumstances of each of the orders is necessary.

[118] Expert Report of Craig McCann, pp. 56-88.

[119] Expert Report of James Rafalski. pp. 41-46.

[120] Expert Report of Craig McCann, pp. 56-57; Deposition of Joseph Rannazzisi, p. 551:4-17 ("Again, just giving me numbers without giving me the -- what is actually going on, what -- where the pharmacy is situated, what the pharmacy is doing, who the pharmacist is -- there's just so many different variables that is -- should it trigger a due diligence analysis? Absolutely. Should it trigger a -- a -- a suspicious order? Maybe. Probably. Because going from 5- to 20,000, that's – that's quite a bit. But until you do the whole analysis, until you look at the pharmacy, until you look at what their patterns were, I can't make that statement.").

79. Finally, for the reasons stated above in Section V.F., any mathematical formula finding that between 19.8% and 99.8% of dosage units shipped to Cuyahoga County and 48.8% to 100.0% of dosage units shipped to Summit County were suspicious is unreasonable.[121] These formulas do not capture unusual or abnormal orders and if applied in real life could have prevented patients from receiving medications that they needed.



Robert L. Hill
Dated: 5/31/2019

[121] Expert Report of James Rafalski, pp. 41-46.